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Interventional Cardiology

Percutaneous Coronary Intervention Versus Coronary Bypass Graft Surgery for Patients With Medically Refractory Myocardial Ischemia and Risk Factors for Adverse Outcomes With Bypass

The VA AWESOME Multicenter Registry: Comparison With the Randomized Clinical Trial

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OBJECTIVES This study was designed to compare the three-year survival after percutaneous coronary intervention (PCI) or coronary artery bypass graft surgery (CABG) in physician-directed and patient-choice registries with the Angina With Extremely Serious Operative Mortality Evaluation (AWESOME) randomized trial results.

BACKGROUND The AWESOME multicenter randomized trial and registry compared the long-term survival after PCI and CABG for the treatment of patients with medically refractory myocardial ischemia and at least one additional risk factor for adverse outcome with CABG. The randomized trial demonstrated comparable three-year survival.

METHODS Over a five-year period (1995 to 2000), 2,431 patients with medically refractory myocardial ischemia and at least one of five risk factors (prior heart surgery, myocardial infarction within seven days, left ventricular ejection fraction <0.35, age >70 years, intra-aortic balloon required to stabilize) were identified. By physician consensus, 1,650 patients formed a physician-directed registry assigned to CABG (692), PCI (651) or further medical therapy (307), and 781 were angiographically eligible for random allocation; 454 of these patients constitute the randomized trial, and the remaining 327 constitute a patient choice registry. Survival for CABG and PCI was compared using Kaplan-Meier curves and log-rank tests.

RESULTS The CABG and PCI 36-month survival rates for randomized patients were 79% and 80%, respectively. The CABG and PCI 36-month survival rates were both 76% for the physician-directed subgroup; comparable survival rates for the patient-choice subgroup were 80% and 89%, respectively. None of the global log-rank tests for survival demonstrated significant differences.

CONCLUSIONS Both registries support the randomized trial conclusion: PCI is an alternative to CABG for some medically refractory high-risk patients. (J Am Coll Cardiol 2002;39:266–73) © 2002 by the American College of Cardiology

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Randomized clinical trials comparing percutaneous coronary intervention (PCI) with coronary artery bypass graft surgery (CABG) have demonstrated comparable long-term survival (1–13). In most trials, relief of angina has been comparable or slightly better with CABG, and the need for further revascularization has favored CABG (1–11). Argentine Randomized Trial of Percutaneous Transluminal Coronary Angioplasty Versus Coronary Artery Bypass Surgery in Multivessel Disease (ERACI) II has extended the pre-

Abbreviations and Acronyms

ACC/AHA = American College of Cardiology/American Heart Association class of lesion grading
AWESOME = Angina With Extremely Serious Operative Mortality Evaluation
CABG = coronary artery bypass graft surgery
CAD = coronary artery disease
IABP = intra-aortic balloon pump
LVEF = left ventricular ejection fraction
MI = myocardial infarction
NYHA = New York Heart Association class of heart failure
PCI = percutaneous coronary intervention (may include stents or atherectomy, in addition or in place of balloon angioplasty only)
SVG = saphenous vein graft
TIMI = Thrombolysis In Myocardial Infarction
VA = U.S. Department of Veterans Affairs

vious PCI versus CABG trials by including the use of stents to treat patients with multivessel disease, the majority of whom had unstable coronary syndromes (10). The recently reported ARTS (Arterial Revascularization Therapies Study) trial also included modern stents and compared quality of life and cost of care end points (11,12).

The 1999 American College of Cardiology/American Heart Association (ACC/AHA) Guidelines for Coronary Artery Bypass Graft Surgery and the editorial that accompanied the publication of ERACI II specified that patient groups with prior CABG, left ventricular ejection fraction <0.35, myocardial infarction (MI) within seven days or intra-aortic balloon pump required to stabilize had not been included in randomized comparisons of CABG and PCI (13,14). These patient groups were not included in ARTS either (11,12). A recently concluded randomized clinical trial, Angina With Extremely Serious Operative Mortality Evaluation (AWESOME), compared CABG and PCI survival among patients with medically refractory ischemia and these risk factors (15,16). AWESOME also included the use of stents and glycoprotein IIb/IIIa receptor-blocking drugs (15,16). The AWESOME trial demonstrated comparable three-year survival for the PCI and CABG groups (16).

The principal purpose of random allocation of subjects is the avoidance of known and unknown selection biases and the avoidance of confounding that would result in noncomparable patient sets assigned to the alternative therapy arms of the study. Randomization should result in a balanced distribution of baseline variables in the alternative therapy arms of the study. The reality of randomized clinical trials is that many health care providers, patients and families do not consent to random allocation, because they do not perceive the alternative therapies to be equally effective. A prospective study of the eligible patients who were directed by physicians not to participate, and of patients deemed acceptable but who declined random allocation, can reveal the extent to which selection bias may obscure treatment differences (17). Registry results also provide insight into current medical decision making (18). This article compares CABG and PCI survival in the AWESOME physician-directed and patient-choice registries to survival in the randomized clinical trial (15,16).

METHODS

The AWESOME protocol, baseline characteristics of randomized patients and three-year outcomes of the randomized cohort have been reported (15,16). The AWESOME trial was a nationwide, prospective randomized clinical trial designed to compare long-term survival with CABG versus PCI for patients with medically refractory myocardial ischemia and increased risk of adverse outcomes with CABG. Patients were enrolled at 16 Veterans Affairs medical centers over a five-year period (1995 to 2000). All 16 sites' institutional review boards and the national VA Human

Table 1. Baseline Comparisons of Randomized, Total Registry, Physician-Directed and Patient-Choice Cohorts

Variable		Random	Registry	Physician-Directed	Patient-Choice
Patients	number	454	1,977	1,650	327
Age	mean	67	67	68	67
Age > 70 years	%	52	53	53	52
Prior PCI	%	23	24	24	23
Prior CABG	%	31	42*	44	36†
Prior MI	%	57	57	57	59
MI <7 days	%	33	32	31	39†
LVEF <0.35	%	21	18	18	16
LVEF	mean	42	44	43	46
IABP	%	2	5	5	3
Smoker	%	35	30	30	35
Diabetes	%	33	33	34	28
Hypertension	%	70	67	68	64
Prior CHF	%	61	69	71	57‡
Prior stroke	%	13	12	12	9
Aspirin	%	94	96	96	95
Heparin	%	84	84	82	90
Beta-blocker	%	79	78	78	77
Ca-blocker	%	33	37	37	33
One-vessel	%	18	22	20	30
Two-vessel	%	41	33	33	37
Three-vessel	%	41	44	47	33‡
Native CAD	%	99	98	98	97
Graft CAD	%	26	33*	35	26‡
LAD >70%	%	89	83	83	83
L main >50%	%	7	18*	19	12‡
ACC/AHA class C	%	75	78	80	67‡
NYHA class III/IV	%	61	69*	71	57‡

*Statistically significant difference between random and registry: $p < 0.01$; †statistically significant difference between physician-directed and patient-choice registry subsets: $p < 0.05$; ‡statistically significant difference between physician-directed and patient-choice registry subsets: $p < 0.01$.

ACC/AHA class = American College of Cardiology/American Heart Association coronary angiographic lesion classification; CABG = coronary artery bypass graft; Ca blocker = calcium channel blocking agent; CAD = coronary artery disease; CHF = congestive heart failure; IABP = intra-aortic balloon pump; LVEF = left ventricular ejection fraction; L main = left main stenosis; LAD = left anterior descending; Native CAD = native vessel coronary artery disease; NYHA = New York Heart Association; PCI = percutaneous coronary intervention.

Table 2. Baseline Clinical and Angiographic Variables of Physician-Directed and Patient-Choice Cohorts by Intervention

		Physician-Directed		Patient-Choice	
		CABG	PCI	CABG	PCI
Patients	n	692	651	95	207
Age	years	69	66	68	66
Age > 70 years	%	63	42*	58	50
Prior PCI	%	17	32*	17	26
Prior CABG	%	22	55*	34	36
Prior MI	%	51	65*	54	61
MI <7 day	%	28	35*	36	41
LVEF <0.35	%	17	19	21	14
LVEF	mean	43	43	45	46
IABP	%	5	7	3	3
Smoker	%	28	32	33	36
Diabetes	%	36	31	22	32
Hypertension	%	69	66	66	64
Prior CHF	%	83	57*	47	60†
Prior stroke	%	11	11	7	9
Three-vessel	%	57	39*	35	30
Native CAD	%	98	98	97	98
SVG CAD	%	21	40*	20	26
LAD >70%	%	92	78*	86	80
L main >50%	%	34	11*	15	10
TIMI no flow	%	44	54*†	51	37
ACC/AHA class C	%	84	75*	57	70†
NYHA class III/IV	%	83	57*	47	60†

*Statistically significant difference between CABG and PCI: p< 0.01; †statistically significant difference between CABG and PCI: p < 0.05.

CABG = coronary artery bypass graft; SVG CAD = disease in saphenous vein graft; TIMI no flow = Thrombolysis In Myocardial Infarction trials class of occlusion with no antegrade flow; PCI = percutaneous coronary intervention. Other abbreviations as in Table 1.

Rights Committee approved the protocol. The conduct of the trial was reviewed annually by these committees.

A total of 22,662 patients were screened, and of these patients, 7,278 did not meet criteria for myocardial ischemia, 5,783 failed to meet criteria for medically refractory myocardial ischemia, and 10,030 had none of the risk factors for adverse outcome with CABG. There were 2,431 clinically eligible patients who met all three clinical criteria. After coronary angiography had been reviewed by both an interventional cardiologist and a surgeon, a total of 781 patients (32%) were acceptable to both operators as candidates for random allocation of revascularization method. These patients were approached for informed consent, and 454 (58%) consented to a randomized choice of revascularization. The 327 patients who refused random allocation elected either CABG or PCI for themselves and are referred to as the patient-choice registry. The 1,650 patients for whom physician consensus would not allow random assignment constitutes a prospective physician-directed registry: 692 were assigned to CABG, 651 were assigned to PCI, and 307 were assigned further medical therapy.

Statistical analysis. Differences in baseline variable frequencies were tested by chi-square tests for proportions. Long-term survival was measured by Kaplan-Meier survival estimates, which were plotted. The statistical significance of global differences between survival curves was judged by log-rank tests. Differences between CABG and PCI 36-month survival were computed along with z-tests of the differences.

Table 3. The Percentage Allocation to CABG Among Physician-Directed and Patient-Choice Patients by High-Risk Baseline Subsets

Baseline Subset		Physician-Directed	Patient-Choice
Overall CABG allocation	%	52	31
Age > 70 years	%	61*	35
Prior PCI	%	36*	23
Prior CABG	%	30*	30
Prior MI	%	45*	29
MI <7 days	%	46*	29
LVEF <0.35	%	49	41
IABP	%	43	31
Smoker	%	48	30
Diabetes	%	55	24
Hypertension	%	53	32
Prior CHF	%	60*	26†
Prior stroke	%	51	27
Three-vessel	%	61*	35
LAD >70	%	56*	33
L main >50	%	77*	41
Native CAD	%	52	31
SVG CAD	%	36*	26
TIMI no flow	%	46	39
ACC/AHA class C	%	54*	27†
NYHA class III/IV	%	60*	26†

Statistically significant difference between overall and risk group percent allocation to CABG: *p < 0.01; †p < 0.05.

SVG CAD = disease in saphenous vein graft; TIMI no flow = Thrombolysis In Myocardial Infarction trials classification of no antegrade flow with occluded vessel. Other abbreviations as in Table 1.

RESULTS

In the entire registry, 83% (1,645/1,977) of patients were revascularized during their index hospitalization. Among those revascularized, 48% (n = 787) received CABG and 52% (n = 858) received PCI. Among physician-directed patients 81% (n = 1,343) were revascularized, 52% (n = 692) by CABG and 48% (n = 651) by PCI. The difference between these two rates is not statistically significant (chi-square; p > 0.10). Among patient-choice patients, 92% (n = 302) were revascularized, 31% (n = 95) selected CABG, and 69% (n = 207) selected PCI. The difference between these two rates is statistically significant (chi-square; p < 0.001).

Methods for CABG and PCI evolved over the course of the study. Left internal mammary artery use increased from 57% in 1995 to 78% by study end, with an overall average of 70%. Stent use increased from 26% of PCI cases in 1995 to 89% in 1999, with an overall average use of 55%. As stent use increased, directional and extractional atherectomy use virtually disappeared. Intra-aortic balloon counter-pulsation declined from 26% in 1995 to 11% in 1999, with an overall use of supportive counter-pulsation of 22%.

Table 1 displays baseline comparisons of randomized and registry patients. The overall registry profile is similar to the randomized profile except for four baseline factors (prior CABG, saphenous vein graft coronary artery disease [SVG

Table 4. CABG and PCI 36-Month Survival, Survival Free of Unstable Angina and Survival Free of Unstable Angina or Repeat Revascularizations

Outcome	CABG	PCI	CABG-PCI Difference	Standard Error
Survival				
Randomized	79%	80%	−1%	5.6%
Physician-directed	76%	76%	0%	2.8%
Patient-choice	80%	89%	−9%	5.9%
Survival free of unstable angina				
Randomized	65%	59%	6%	8.4%
Physician-directed	66%	51%	15%*	5.0%
Patient-choice	63%	64%	−1%	11%
Survival free of unstable angina or repeat revascularization				
Randomized	61%	48%	13%	10%
Physician-directed	63%	46%	17%	12%
Patient-choice	60%	57%	3%	5%

*Statistically significant difference $p < 0.01$.
CABG = coronary artery bypass graft; PCI = percutaneous coronary intervention.

CAD], left main >50% and New York Heart Association [NYHA] class III/IV).

Table 2 displays baseline prevalence rates and means of clinical and angiographic risk factors in the two registry subgroups allocated to CABG or PCI. Physician-directed patients allocated to CABG had substantially higher prevalence rates for age >70 years, prior congestive heart failure, three-vessel disease, left anterior descending coronary artery >70%, left main >50%, ACC/AHA class C and NYHA class III/IV compared with the rates for those allocated to PCI. Physician-directed patients assigned to PCI had substantially higher prevalence rates for prior PCI, prior CABG, SVG CAD, Thrombolysis in Myocardial Infarction (TIMI) no flow and prior MI compared with the prevalence rates for those allocated to CABG.

Table 3 presents the percentage of patients allocated to CABG by risk factors for the physician-directed and the patient-choice subsets. Among physician-directed patients, five risk factors (prior PCI, prior CABG, prior MI, MI <7 days and SVG CAD) are associated with a physician preference for PCI and five risk factors (age >70 years; prior CHF, three-vessel disease, left main >50% and NYHA class III/IV) are associated with a physician preference for CABG. Single-vessel patients were preferentially directed to PCI; patients with two-vessel disease were split comparably between CABG and PCI. The differences between these rates and the overall CABG allocation rate for physician-directed patients are statistically significant.

Table 4 presents Kaplan-Meier estimates of CABG and PCI: 36-month survival, 36-month survival free of unstable angina and 36-month survival free of unstable angina or repeat revascularization for the randomized patients and the physician-directed and patient-choice registry subgroups. The table lists CABG-PCI 36-month survival differences and the standard errors of the differences. None of the 36-month survival differences is statistically significant.

Kaplan-Meier estimates of CABG and PCI survival, survival free of unstable angina and survival free of unstable angina or repeat revascularizations for the physician-directed and patient-choice registries are shown in Figures 1 to 6 along with the global log-rank test. The yearly number of patients with CABG and PCI and the yearly survival estimates appear at the bottom of each plot. The CABG and PCI plots appear parallel post six-months for all traits.

The in-hospital stroke rates for CABG and PCI were 1%

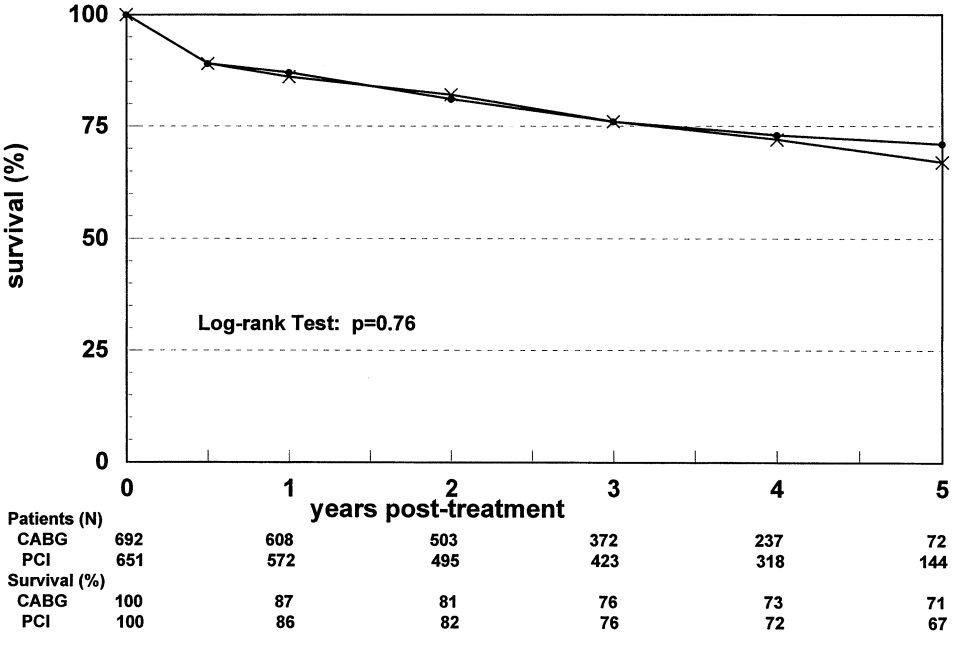
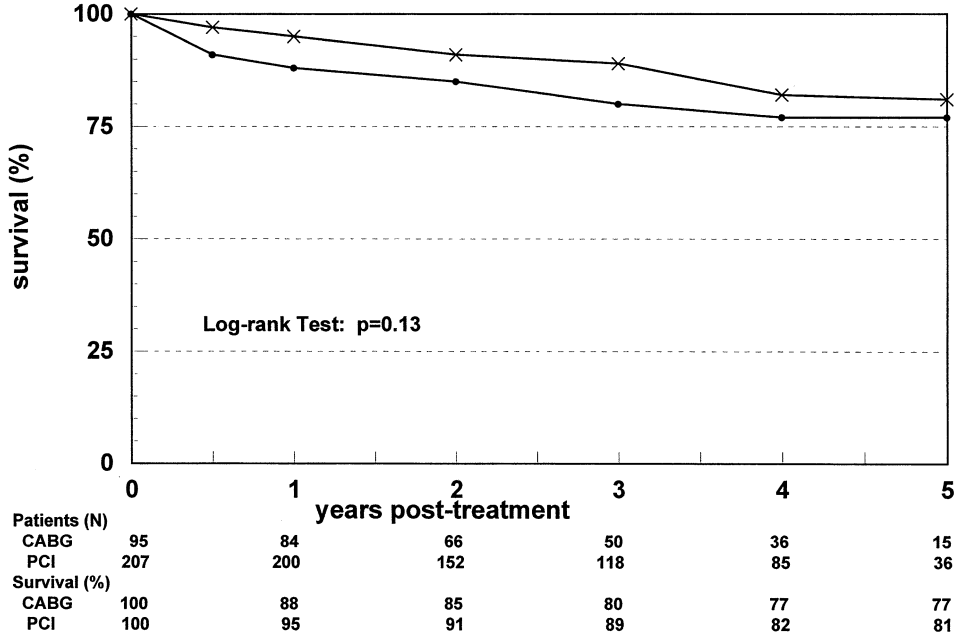


Figure 1. Kaplan-Meier plots of survival for coronary artery bypass graft surgery (CABG) **(circle)** versus percutaneous coronary intervention (PCI) **(×)** in physician-directed registry. Numbers of patients and survival are given at the bottom.



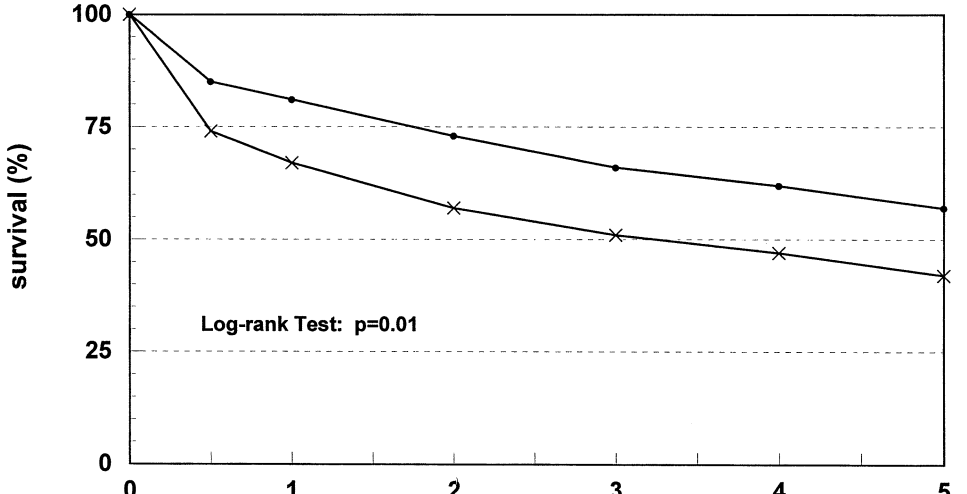
Patients (N)						
CABG	95	84	66	50	36	15
PCI	207	200	152	118	85	36
Survival (%)						
CABG	100	88	85	80	77	77
PCI	100	95	91	89	82	81

Figure 2. Kaplan-Meier plots of survival for coronary artery bypass graft surgery (CABG) **(circle)** versus percutaneous coronary intervention (PCI) **(×)** in patient-choice registry. Numbers of patients and survival are given at the bottom.

and 1%, respectively, in the randomized cohort, 3% and 0.3%, respectively, ($p < 0.01$) in the physician-directed registry and 5% and 1%, respectively, (NS) in the patient-choice registry.

DISCUSSION

The AWESOME registry results extend the randomized trial conclusion that CABG and PCI are both options for medically refractory patients with angina having prior CABG, recent MI, poor left ventricular function, age >70 or instability necessitating intra-aortic balloon counterpulsation (IABP) (15,16). The randomized cohort plus the two registries include 100% of the patients who met all three pre-established clinical criteria for the trial at the participating sites. Survival patterns for CABG and PCI are similar in the randomized cohort and in both registry cohorts. Survival free of repeat angina episodes is lower in the PCI patients in the physician-directed registry but not the patient-choice registry; the differences are not large and



Patients (N)						
CABG	692	561	421	358	223	72
PCI	651	468	349	306	220	120
Survival (%)						
CABG	100	81	73	66	62	57
PCI	100	67	57	51	47	42

Figure 3. Kaplan-Meier plots of survival free of unstable angina for coronary artery bypass graft surgery (CABG) **(circle)** versus percutaneous coronary intervention (PCI) **(×)** in physician-directed registry. Numbers of patients and survival are given at the bottom.

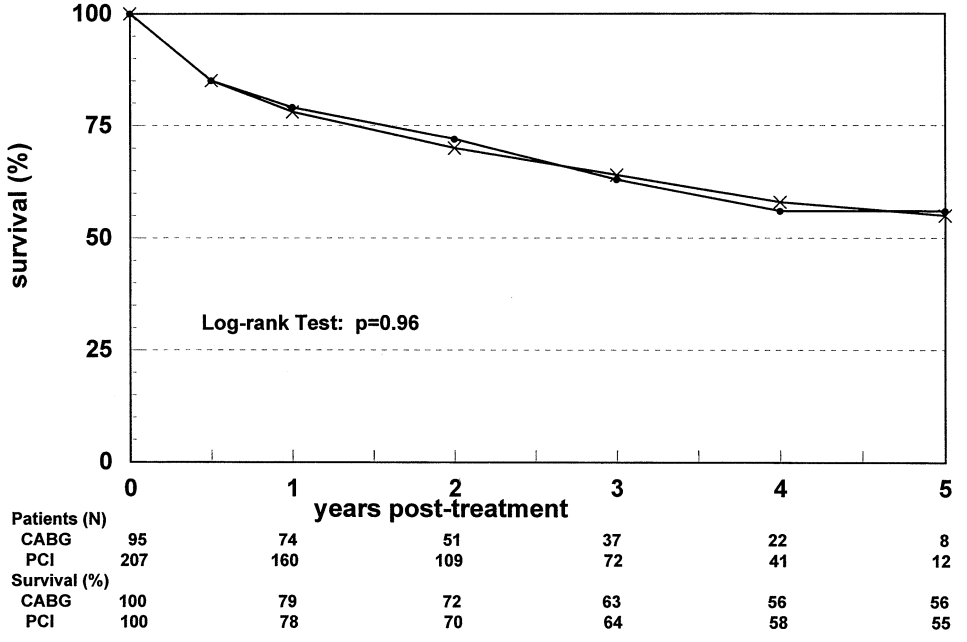


Figure 4. Kaplan-Meier plots of survival free of unstable angina for coronary artery bypass graft surgery (CABG) **(circle)** versus percutaneous coronary intervention (PCI) **(×)** in patient-choice registry. Numbers of patients and survival are given at the bottom.

occur in the first six months. The physician-directed and patient-choice registry cohorts display the current attitudes of physicians and patients as to the appropriate choice of revascularization for high-risk patient subsets.

Physician direction. The prospectively gathered registry of patients for whom physicians would not permit random allocation provides some insight into factors associated with the choice of revascularization. Five clinical factors (older age, three-vessel disease, left main disease, NYHA class III/IV and proximal left anterior descending disease) appear to have influenced the physicians to direct patients toward CABG. Patients with single-vessel disease were preferentially directed to PCI, whereas patients with two-vessel disease were split comparably.

The risk factors of prior MI, prior CABG, prior PCI and SVG CAD were all associated with physician direction to PCI. The conventional risk factors of smoking, hypertension, low left ventricular ejection fraction (LVEF < 0.35) or

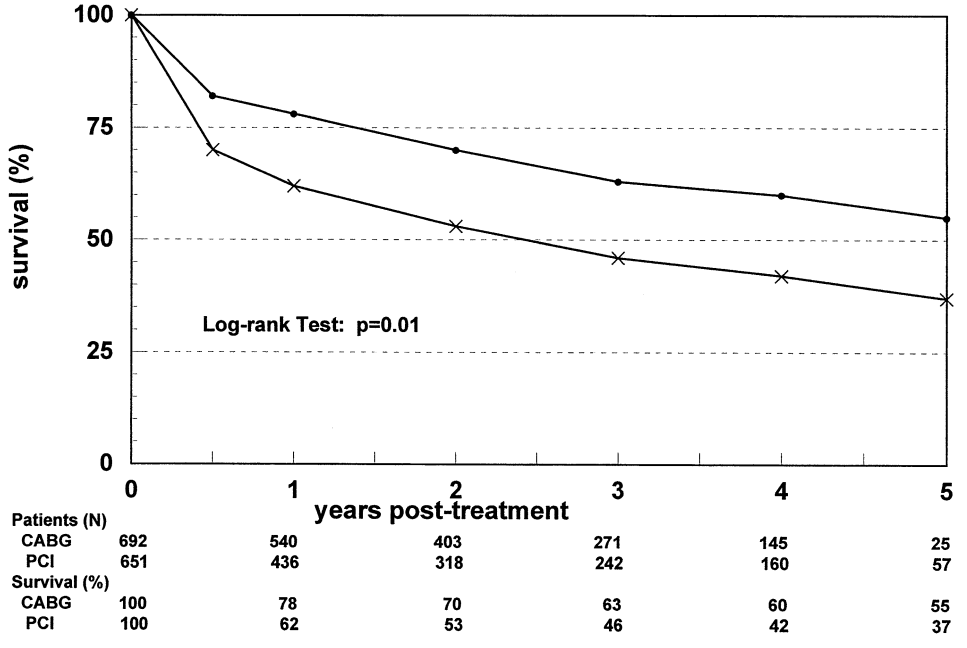


Figure 5. Kaplan-Meier plots of survival free of unstable angina and repeat revascularization for coronary artery bypass graft surgery (CABG) **(circle)** versus percutaneous coronary intervention (PCI) **(×)** in physician-directed registry. Numbers of patients and survival are given at the bottom.

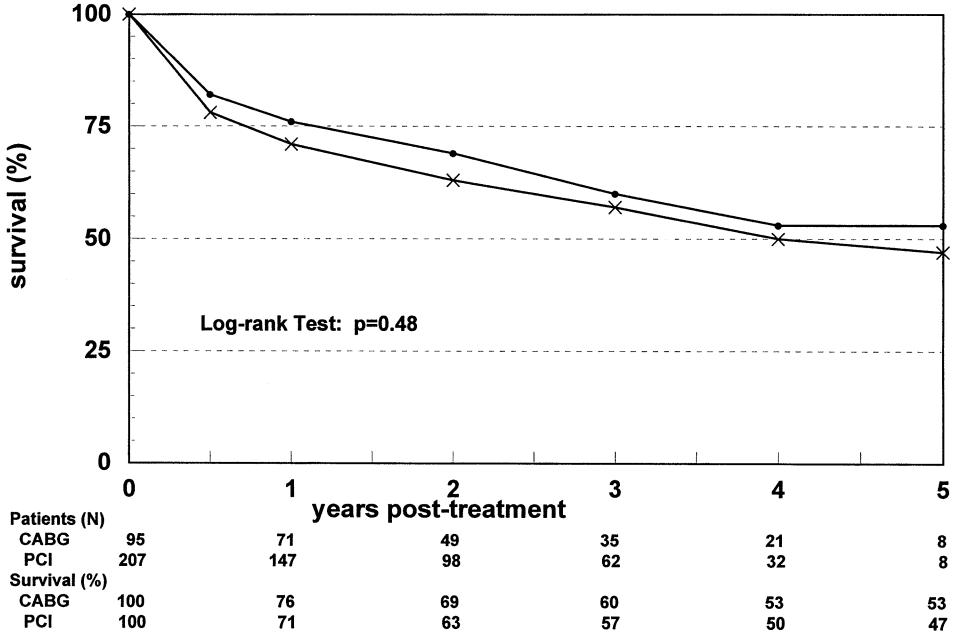


Figure 6. Kaplan-Meier plots of survival free of unstable angina and repeat revascularization for coronary artery bypass graft surgery (CABG) **(circle)** versus percutaneous coronary intervention (PCI) **(×)** in patient-choice registry. Numbers of patients and survival are given at the bottom.

a requirement for IABP do not appear to have been used to preferentially direct patients to CABG or PCI. We are not aware of published data from any other study that has compared CABG to PCI for several of these important high-risk subgroups, such as patients with prior CABG or patients with very low LVEF (13–16). Nonetheless, physicians often must choose a course of action when trial-based guidelines do not exist.

Patient choice. The registry patients deemed acceptable for both CABG and PCI by their respective operators (and often referring physicians) are inherently lower risk than the physician-directed cohort. These patients provide insight into the factors associated with "patient choice." With the profusion of medical information available via the Internet, television and radio, patient choice often includes some physician direction. The majority of these patients chose PCI.

Time trends in revascularization methodology. During the five years of the study, the use by our surgeons of left and right internal mammary arteries and radial arteries increased, perhaps reflecting increased comfort with high-risk cases. During the same period, stent and glycoprotein IIb/IIIa blocker usage sharply increased in the study. As stent use increased, atherectomy (all three types) use decreased; indeed, both directional and transluminal extraction catheter use nearly disappeared. Thus, this trial reflects the continuous evolution of CABG and PCI revascularization techniques during the period from 1995 to 2000.

Limitations. The first limitation of any registry is that physician and patient selection is biased selection. Accordingly, the registry provides a look at the systematic (non-random) thinking of physicians and patients. Neither stroke nor MI was systematically evaluated as an end point in a blinded or core-laboratory controlled fashion. The 1,977-patient registry is comparable in size to the BARI registry (although the randomized trial is smaller), but not nearly as large as such registries as the Veterans Affairs Continuous Improvement program in cardiac surgery (17–22). There were few women in the randomized trial or in the registry.

Summary and implications. The registry data extend the results of the AWESOME randomized trial, suggesting that PCI or CABG may relieve medically refractory ischemia among patients with risk factors for adverse outcomes with CABG. The preferences for CABG or PCI within high-risk subgroups reflect an overall weighing of the different benefits and risks associated with CABG or PCI on the part of the physicians and/or patients.

Acknowledgments

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The participants in the Veterans Affairs Cooperative Study #385: AWESOME are listed in reference 16.

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